

**IN THE DRAWINGS:**

FIG. 8 has been corrected as shown in the Replacement Drawing Sheet and as shown in red in the Annotated Sheet Showing Changes in the attached Appendix.

FIG. 9 has been corrected as shown in the Replacement Drawing Sheet and as shown in red in the Annotated Sheet Showing Changes in the attached Appendix.

REMARKS

This Amendment is submitted in response to the Final Rejection dated March 14, 2006. In the Office Action, the Patent Office requires Applicant to provide information under 37 CFR §1.105 which the Patent Office has determined is reasonably necessary to the examination of the application. Additionally, the Patent Office refused to consider an Information Disclosure Statement (hereinafter "the IDS") filed on January 3, 2006 and asserts that the IDS fails to comply with 37 CFR 1.98(a)(2). Further, the Patent Office objected to the drawings under 37 CFR §1.84(p)(5) because the drawings include a reference character not mentioned in the description. Still further, the Patent Office objected to the drawings under 37 CFR §1.83(a) for failing to show every feature of the invention specified in the claims.

The Patent Office rejected Claims 5, 33 and 68 under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement; and rejected Claims 1 and 3-13 for failing to comply with the written description requirement. Further, the Patent Office rejected Claims 5, 7, 10, 18, 22, 37, 45, 73 and 79 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Patent Office rejected Claims 1, 5-10, 12, 13, 55, 56, 71, 73-75 and 77-81 under 35 U.S.C. §102(b) as being anticipated by

U.S. Patent No. 4,448,735 to *Huge*; and rejected Claims 40, 44-47, 50, 52, 57-59, 61 and 64-68 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,898,535 to *Bergersen* (hereinafter "the '535 patent"). Further, the Patent Office rejected Claims 1, 3-10, 12-15, 18-23, 27-29, 31-37, 39, 48, 49, 51, 53, 54, 56, 62, 63, 70, 71 and 73-82 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of U.S. Patent No. 4,983,334 to *Adell*; rejected Claims 11, 26 and 38 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of *Adell* and further in view of U.S. Patent No. 5,876,199 to *Bergersen* (hereinafter "the '199 patent"); rejected Claims 24, 55 and 72 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of *Adell* and further in view of U.S. Patent No. 3,950,851 to *Bergersen* (hereinafter "the '851 patent"); rejected Claim 41 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '851 patent; and rejected Claim 60 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '119 patent.

By the present Amendment, Applicant amended Claims 1, 5, 7, 10, 14, 18, 22, 24, 27, 33, 37, 40, 41, 45, 51, 53, 54, 57, 64, 68, 71, 73, 77 and 79. Applicant asserts that the amendments to the claims and the remarks that follow overcome the objections and rejections made by the Patent Office and place the application in condition for allowance. Notice to that effect is requested.

With respect to the request for information from Applicant in accordance with 37 CFR §1.105 and MPEP §704.11(a) subsection G, Applicant has identified co-pending applications and related patents which may have claims that may present double patenting issues with the present application.

In the Office Action, the Patent Office asserts:

In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant (or the assignee) is respectfully requested to disclose all co-pending applications and related patents (please see the non-exhaustive list below of applications and issued patents that the USPTO believes may be related) and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims. This requirement is reasonably necessary to examination because, based on an initial review of the applications, there is a significant degree of overlap in claimed subject matter, thus requiring an analysis of commonality of claimed subject matter to determine patentability under 35 U.S.C. §101 double patenting and/or obviousness type double patenting. Because the applicant (or the assignee) is presumably far more cognizant of the contents of the claims in these applications than any Office staff, and has access to the source documents by which such comparison could be done better than within the Office, it is reasonable to require the applicant to provide the information needed to determine the commonality among the claims. Non-exhaustive list of possible related co-pending applications and patents: 09/546,685; 09/686,142; 10/447,098; 10/447,099; 10/449,292; 10/449,312; 10/665,326; 10/665,441; 10/760,604; and 11/257,330.

With respect to patents related to the present application, U.S. Patent Nos. 6,626,664 (hereinafter "the '664 patent") and 6,582,225 (hereinafter "the '225 patent") issued from U.S. Serial Nos. 09/546,685 and 09/686,142, respectively. Applicant asserts that subject matter of the issued claims of the '664 patent and the

'225 patent is different than and is uncommon with subject matter of the pending claims of the present application. Therefore, Applicant asserts that the pending claims of the present invention do not present double patenting issues with the claims of the '664 patent and the '225 patent.

With respect to co-pending applications, Applicant asserts that the subject matter of the pending claims of U.S. Serial Nos. 10/447,098; 10/447,099; 10/449,292; 10/449,312; 10/665,326; 10/665,441; and 11/257,330 is different than and is uncommon with the subject matter of the pending claims of the present application. Therefore, Applicant asserts that the pending claims of the present invention do not present double patenting issues with the pending claims of U.S. Serial Nos. 10/447,098; 10/447,099; 10/449,292; 10/449,312; 10/665,326; 10/665,441; and 11/257,330.

With respect to co-pending application U.S. Serial No. 10/449,292 (hereinafter "the '292 application"), Applicant asserts that the subject matter of pending Claims 7, 21 and 100 of the '292 application may be similar to or may be common with the subject matter of the pending claims of the present invention. Therefore, Applicant asserts that the pending claims of the present invention may present double patenting issues with the pending claims of the '292 application.

With respect to the IDS, the Patent Office asserts that "the information disclosure statement filed 03 January 2006 fails to

comply with 37 CFR §1.98(a)(2), which requires a legible copy of each cited foreign patent document. It has been placed in the application file, but the information referred to therein has not been considered." Applicant asserts that the foreign patent documents cited in the IDS refer to international applications which were filed in the U.S. Patent Office as a Receiving Office under the provisions of the Patent Cooperation Treaty.

Further, Applicant asserts that the foreign patent documents cited in the IDS correspond directly to the co-pending applications for the present application which were identified by the Patent Office in Paragraph 4 on Page 3 of the Office Action. International Application No. PCT/US03/16725 corresponds directly to U.S. Serial No. 10/447,099; International Application No. PCT/US03/16733 corresponds directly to U.S. Serial No. 10/447,098; International Application No. PCT/US03/17163 corresponds directly to U.S. Serial No. 10/449,312; International Application No. PCT/US03/17196 corresponds directly to U.S. Serial No. 10/449,292; International Application No. PCT/US03/029667 corresponds directly to U.S. Serial No. 10/665,326; and International Application No. PCT/US03/029662 corresponds directly to U.S. Serial No. 10/665,441. Still further, Applicant asserts that the Patent Office has access to the foreign patent documents cited in the IDS and/or the corresponding U.S. patent applications and should have reviewed and

considered the International Applications cited in the IDS prior to mailing the Office Action.

In view of the foregoing, Applicant asserts that submission of the International Applications cited in the IDS is not necessary since the Patent Office has access to those applications and/or their corresponding U.S. application. However, for the purposes of completeness, Applicant submits a Second Supplemental IDS with this Amendment including copies of the International Applications cited in the Second Supplemental IDS. Applicant requests that citation and examination of the references identified in the Second Supplemental IDS be made during the course of examination of this application.

In the Office Action, the Patent Office objected to the drawings under 37 CFR §1.83(a) for failing to show every feature of the invention specified in the claims. Namely, the Patent Office asserts that the drawings fail to show an embodiment wherein the first end is made of a stiffer material than the second end. In response to the objection, Applicant asserts that an embodiment having a first end which is made of a stiffer material than a second end is disclosed on page 20 of the application. Lines 7-12 on page 20 of the application state: "In another embodiment, a front portion 80 of the dental appliance 70 may be constructed from a soft, adhering material; a rear portion 82 of the dental appliance 82 may be constructed from a stiffer material, such as,

for example, a hard plastic or rubber." Applicant submits that the objection is improper and should be withdrawn. Notice to that effect is requested.

Further, the Patent Office objected to the drawings under 37 CFR §1.84(p)(5) for failing to include reference signs 115, 117, 119 and 121 which are mentioned in the description. In response to the objection, Applicant amended FIGS. 8 and 9 to show the lingual shields 115, 117 and the buccal shields 119, 121 as set forth on page 22 of the description. Applicant also amended FIGS. 8 and 9 to show the rear portion 123 of the upper shell 110 and the rear portion of the lower shell 120.

The lingual shields 115, 117, the buccal shields 119, 121 and rear portions 123, 125 are disclosed in the specification as filed. Specifically, page 22, lines 2-5 state: "The upper shell 110 and/or the lower shell 120 may have roughened, or coarse surfaces 114, 122, respectively, along the lingual shields 115, 117 and/or buccal shields 119, 121 to secure the reline material 132." Further, page 22, lines 8-10 state: "The lingual shields 115, 117 and the buccal shields 119, 121 may have a mark 112 placed on the roughened surfaces 114, 122." Moreover, page 22, line 35 through page 23, line 2 state: "A rear portion 123, 125 of the upper shell 110 and/or the lower shell 120 may then be forcibly pushed down on the teeth." Applicant submits that the amendment to FIGS. 8 and 9



overcomes the objection by the Patent Office. Notice to that effect is requested.

With respect to the rejection of Claims 5, 33 and 68 under 35 U.S.C. §112, first paragraph, Applicant respectfully submits that the rejection has been overcome by the amendments to Claims 5, 33 and 68 and for the reasons that follow.

In the Office Action, the Patent Office asserts:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not recite what a "reline material" is or what properties it possesses or give examples of materials which could be used as a reline material. As such one skilled in the art would be unable to make and use the invention as they would not know what to use as such "reline material".

Claim 5, as amended, defines dental appliance having a mark on the interior surface indicating an amount of reline material in contact with the interior surface wherein the interior surface prevents the reline material from disengaging from the generally U-shaped base.

Claim 33, as amended, defines a dental appliance having a mark on the upper base indicating an amount of a reline material in contact with the upper base wherein upper base receives the reline material wherein the reline material prevents the upper base from dislodging from the upper teeth of the user when the upper base is worn on the upper teeth.

Claim 68, as amended, defines a dental appliance having a mark on the lower base indicating an amount of a reline material in contact with the lower base wherein the lower base receives the reline material wherein the reline material prevents the lower base from dislodging from the lower teeth of the user when the lower base is worn on the lower teeth of the user.

The amendments to Claims 5, 33 and 68 further define the subject matter which the Patent Office asserts as not described in the specification in such a way as to enable one skilled in the art which it pertains to practice the invention as set forth on page 5 of the Office Action. Accordingly, the rejection of Claims 5, 33 and 68 under 35 U.S.C. §112, first paragraph, has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 1 and 3-13 under 35 U.S.C. §112, first paragraph, Applicant respectfully submits that the rejection has been overcome by the amendment to independent Claim 1 and for the reasons that follow.

In the Office Action, the Patent Office asserts:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not disclose or otherwise provide support for the second, less stiff material of the second end of the base adhering the base to the teeth. Thus such recitation constitutes new matter.

Independent Claim 1, as amended, defines a generally U-shaped base having the first end which has a rear portion which is made from a first material and the second end which has a front portion which is made from a second material wherein the first material is stiffer than the second material wherein the second material moves at least one of the upper teeth of the user or at least one of the lower teeth of the user when the base is worn in the mouth of the user.

The amendment to Claim 1 further defines the subject matter which the Patent Office asserts as not described in the specification in such a way as to enable one skilled in the art which it pertains to practice the invention as set forth on page 5 of the Office Action. As set forth above, lines 7-12 on page 20 of the application state: a front portion 80 of the dental appliance 70 may be constructed from a soft, adhering material; a rear portion 82 of the dental appliance 82 may be constructed from a stiffer material, such as, for example, a hard plastic or rubber." Accordingly, the rejection of Claims 1 and 3-13 under 35 U.S.C. §112, first paragraph, has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 5, 7, 10, 18, 22, 37, 45, 73 and 79 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention,

Applicant submits that the amendments to Claims 5, 7, 10, 18, 22, 37, 45, 73 and 79 overcome the rejection by the Patent Office.

In the Office Action, the Patent Office asserts:

Claim 5, lines 1 and 2, "the reline material" lacks a prior antecedent.

Claim 7 recites "the first material has a lesser degree of rigidity than the second material" which contradicts base claim 1.

Claim 10 recites that "the base increases in rigidity from the first end to the second end" which contradicts base claim 1.

Claim 18, line 2, it is unclear which of the previously recited concave portions is being referred to by "the concave portion".

Claim 22 recites "the first material has a lesser degree of rigidity than the second material" which contradicts base claim 14.

Claim 37 recites that "the base increases in rigidity from the first end to the second end" which contradicts base claim 27.

Claim 45, line 2, it is unclear which of the previously recited occlusal surface is being referred to by "the occlusal surface".

Claim 73 recites "the first material has a lesser degree of rigidity than the second material" which contradicts base claim 71.

Claim 79 recites "the first material has a lesser degree of rigidity than the second material" which contradicts base claim 77.

Claim 5, as amended, defines a dental appliance having a mark on the interior surface indicating an amount of reline material in contact with the interior surface.

Claim 7, as amended, defines a dental appliance having the first material which has a greater degree of rigidity than the second material.

Claim 10, as amended, defines a dental appliance having the base which increases in rigidity from the front portion to the rear portion.

Claim 18, as amended, defines a system having a shield extending from the concave portion of the upper base or the lower base.

Claim 22, as amended, defines a system having the first material which has a greater degree of rigidity than the second material.

Claim 37, as amended, defines a dental appliance having the lower base which decreases in rigidity from the first end to the second end.

Claim 45, as amended, defines a dental appliance having the upper occlusal surface and the lower occlusal surface which are flat.

Claim 73, as amended, defines a dental appliance having the first material which has a greater degree of rigidity than the second material.

Claim 79, as amended, defines a dental appliance having the first material which has a greater degree of rigidity than the second material.

Applicant submits that the rejection of Claims 5, 7, 10, 18, 22, 37, 45, 73 and 79 under 35 U.S.C. §112, second paragraph, has been overcome. Notice to that effect is requested.

In the Office Action, the Patent Office rejected Claims 1, 5-10, 12, 13, 55, 56, 71, 73-75 and 77-81 under 35 U.S.C. §102(b) as being anticipated by *Huge*. More specifically, the Patent Office alleges that:

*Huge* discloses a dental appliance comprising a generally U-shaped base having a length defined between a first end and a second end and an occlusal surface which contacts the teeth when the device is placed in the mouth. The base further has an interior surface which substantially surrounds a surface of at least one tooth. The first end 28 is made of a first material and the second end is made of a second material. Either end may be harder, and thus stiffer, than the other (see col. 3, lines 40-44).

As set forth above, independent Claim 1, as amended, requires a generally U-shaped base wherein first end has a rear portion which is made from a first material and the second end has a front portion which is made from a second material wherein the first material is stiffer than the second material wherein the second material moves at least one of the upper teeth of the user or at least one of the lower teeth of the user when the base is worn in the mouth of the user.

Independent Claim 71, as amended, requires a generally U-shaped base wherein the occlusal surface treats the malocclusion wherein the malocclusion is associated only with the upper teeth wherein the base is made of a first material and a second material wherein the first material is stiffer than the second material wherein the base is attachable to at least one of the upper teeth of the user via the first material wherein the second material

moves at least one of the upper teeth of the user. Further, Claim 71 requires two or more sockets formed within the top side of the base wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the upper teeth wherein the bottom side of the base does not contact the bottom teeth of the user when the base is worn in the mouth of the user.

Independent Claim 77, as amended, requires a generally U-shaped base having the occlusal surface which treats the malocclusion wherein the malocclusion is associated only with the lower teeth wherein the base is made of a first material and a second material wherein the first material is stiffer than the second material wherein the second material of the base moves at least one of the lower teeth of the user. Further, Claim 77 requires two or more sockets formed within the bottom side of the base wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the lower teeth wherein the top side of the base does not contact the top teeth of the user when the base is worn in the mouth of the user.

Huge merely discloses a tooth positioner having several integral tooth engaging portions formed of materials having different hardness, the harder portions of which assist in anchoring the tooth positioner in its proper position in the patient's mouth. Further, Huge discloses a method having the steps

of enclosing dental counterpart of the mold to form a first portion of the positioner and placing at least one other material into the mold in interfacing relation to the first portion to form a second portion of the tooth positioner. Moreover, *Huge* discloses the step of curing the several materials into an integral body before extracting the positioner from the mold.

Nowhere does *Huge* teach or suggest a generally U-shaped base wherein first end has a rear portion which is made from a first material and the second end has a front portion which is made from a second material wherein the first material is stiffer than the second material wherein the second material moves at least one of the upper teeth of the user or at least one of the lower teeth of the user when the base is worn in the mouth of the user as required by Claim 1.

Further, nowhere does *Huge* teach or suggest a generally U-shaped base wherein the occlusal surface treats the malocclusion wherein the malocclusion is associated only with the upper teeth wherein the base is made of a first material and a second material wherein the first material is stiffer than the second material wherein the base is attachable to at least one of the upper teeth of the user via the first material wherein the second material moves at least one of the upper teeth of the user as required by Claim 71. Still further, nowhere does *Huge* teach or suggest two or more sockets formed within the top side of the base wherein at



least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the upper teeth wherein the bottom side of the base does not contact the bottom teeth of the user when the base is worn in the mouth of the user as required by Claim 71.

Moreover, nowhere does *Huge* teach or suggest a generally U-shaped base having the occlusal surface which treats the malocclusion wherein the malocclusion is associated only with the lower teeth wherein the base is made of a first material and a second material wherein the first material is stiffer than the second material wherein the second material of the base moves at least one of the lower teeth of the user as required by Claim 77. Furthermore, nowhere does *Huge* teach or suggest two or more sockets formed within the bottom side of the base wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the lower teeth wherein the top side of the base does not contact the top teeth of the user when the base is worn in the mouth of the user as required by Claim 77. Therefore, *Huge* clearly does not teach the elements required by Claims 1, 71 and 77, as amended.

Under 35 U.S.C. §102(b), anticipation requires that a single reference discloses each and every element of Applicant's claimed invention. *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1479, 1 USPQ 2d. 1241, 1245 (Fed. Cir. 1986). Moreover,

anticipation is not shown even if the differences between the claims and the reference are "insubstantial", and one skilled in the art could supply the missing elements. *Structure Rubber Products Co. v. Park Rubber Co.*, 749 F.2d. 707, 716, 223 USPQ 1264, 1270 (Fed. Cir. 1984).

Since *Huge* fails to disclose the elements specifically defined in amended independent Claims 1, 71 and 77, Applicant asserts that the rejection of Claims 1, 5-10, 12, 13, 55, 56, 71, 73-75 and 77-81 under 35 U.S.C. §102(b) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 40, 44-47, 50, 52, 57-59, 61 and 64-68 under 35 U.S.C. §102(b) as being anticipated by the '535 patent, Applicant submits that the rejection has been overcome in view of the foregoing amendments and the remarks that follow.

Independent Claim 40, as amended, requires a generally U-shaped upper base which is made from a first material and a second material wherein the first material is stiffer than the second material and a generally U-shaped lower base which is made from the first material and the second material. Further, Claim 40 requires a hinge integrally formed with the upper base and the lower base wherein the hinge connects the upper base and the lower base wherein the upper occlusal surface adheres to one of the upper teeth via the first material of the upper base and further wherein

the lower occlusal surface moves one of the lower teeth via the first material of the upper base.

Independent Claim 57, as amended, requires a generally U-shaped upper base and a generally U-shaped lower connected to the upper base wherein the front portion of the upper base and the lower base is made from a first material and the rear portion of the upper base and the lower base is made from a second material wherein the first material is stiffer than a second material.

Independent Claim 64, as amended, requires a generally U-shaped upper base and a generally U-shaped lower base wherein the upper base and the lower base are made from a first material and a second material wherein the first material is stiffer than the second material. Further, Claim 64 requires a hinge integrally formed with the upper base and the lower base wherein the hinge connects the upper base and the lower base wherein the hinge and the first material of the upper base and the lower base attach the lower base and the upper base to the mouth of the user.

The '535 patent merely teaches a removable orthodontic appliance provided with a means for retaining the appliance within the user's mouth. The device can be constructed by slitting the plastic or other resilient material appliance along a center parting line (along the direction of the occlusal plane) either at the time of molding or afterwards.

Nowhere does the '535 patent teach or suggest a generally U-shaped upper base which is made from a first material and a second material wherein the first material is stiffer than the second material and a generally U-shaped lower base which is made from the first material and the second material as required by Claim 40. Further, nowhere does the '535 patent teach or suggest a hinge integrally formed with the upper base and the lower base wherein the hinge connects the upper base and the lower base wherein the upper occlusal surface adheres to one of the upper teeth via the first material of the upper base and further wherein the lower occlusal surface moves one of the lower teeth via the first material of the upper base as required by Claim 40. Still further, nowhere does the '535 patent teach or suggest a generally U-shaped upper base and a generally U-shaped lower connected to the upper base wherein the front portion of the upper base and the lower base is made from a first material and the rear portion of the upper base and the lower base is made from a second material wherein the first material is stiffer than a second material as required by Claim 57.

Moreover, nowhere does the '535 patent teach or suggest a generally U-shaped upper base and a generally U-shaped lower base wherein the upper base and the lower base are made from a first material and a second material wherein the first material is stiffer than the second material as required by Claim 64.

Furthermore, nowhere does the '535 patent teach or suggest a hinge integrally formed with the upper base and the lower base wherein the hinge connects the upper base and the lower base wherein the hinge and the first material of the upper base and the lower base attach the lower base and the upper base to the mouth of the user as required by Claim 64. Therefore, the '535 patent does not teach an dental appliance as required by Claims 40, 57 and 64, as amended.

Since the '535 patent fails to disclose an orthodontic appliance as specifically defined in Claims 40, 57 and 64, Applicant asserts that the rejection of Claims 40, 44-47, 50, 52, 57-59, 61 and 64-68 under 35 U.S.C. §102(b) has been overcome and should be withdrawn. Notice to that effect is requested.

In the Office Action, the Patent Office rejected Claims 1, 3-10, 12-15, 18-23, 27-29, 31-37, 39, 48, 49, 51, 53, 54, 56, 62, 63, 70, 71 and 73-82 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of Adell. More specifically, the Patent Office alleges that:

Bergersen '535 discloses the invention essentially as claimed except for the first end being of a stiffer material than the second end. Adell discloses a dental appliance wherein either or both ends may be made of a harder, less resilient material than the remainder of the device (see col. 6, lines 17-31). Adell further discloses that the U-shaped base may be sized so as not to cover the full arch (col. 6, lines 32-37). It would have been obvious to form the device of Bergersen '535 the first end being of a stiffer material than the second end as taught by Adell in

order to anchor the appliance to the molars on one side and not cause them to move. Regarding Claims 23 et al. to form the device so it is sized to cover only part of the arch would have been further obvious also in view of Adell in order to cover only those teeth that need treatment.

Independent Claim 1, as amended, requires a generally U-shaped base having an upper occlusal surface and a lower occlusal surface which are sized to receive the upper teeth or the lower teeth of the user wherein the upper occlusal surface contacts the upper teeth of the user when the base is placed within the mouth wherein the lower occlusal surface contacts the lower teeth of the user when the base is placed within the mouth of the user wherein the base has an interior surface which substantially surrounds a surface of at least one of the upper teeth and at least one of the lower teeth.

Independent Claim 14, as amended, requires a first dental appliance having a generally U-shaped upper base and a second dental appliance having a generally U-shaped lower base wherein the first dental appliance and the second dental appliance are made from a first material and a second material wherein the first material is stiffer than the second material wherein a front portion of the upper base and the lower base is adjacent to the second material and further wherein a rear portion of the upper base and the lower base is adjacent to the first material. Further, Claim 14 requires a hinge connecting the second material of the upper base to the second material of the lower base wherein

the hinge is made from a third material wherein the third material is stiffer than the first material.

Independent Claim 27, as amended, requires a generally U-shaped upper base and a generally U-shaped lower base wherein the upper occlusal surface and the lower occlusal surface are sized to receive the upper teeth or the lower teeth of the user wherein the front portion of the upper base and the lower base is adjacent to the second material and further wherein the rear portion of the upper base and the lower base is adjacent to the first material. Further, Claim 27 requires that the hinge and the first material of the upper base and the lower base attach the upper base and the lower base to the mouth of the user.

Independent Claim 54, as amended, requires the step of determining an amount of time the user is required to place the dental appliance within the mouth on a periodic basis wherein the dental appliance has a generally U-shaped base wherein the base has an upper occlusal surface and a lower occlusal surface which is located opposite to the upper occlusal surface wherein the upper occlusal surface and the lower occlusal surface have sockets formed within the base sized to receive at least one or more teeth of the user.

Independent Claim 71, as amended, requires a generally U-shaped base wherein the base is made of a first material and a second material wherein the first material is stiffer than the

second material wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the upper teeth wherein the bottom side of the base does not contact the bottom teeth of the user when the base is worn in the mouth of the user.

Independent Claim 77, as amended, requires a generally U-shaped base which is made of a first material and a second material wherein the first material is stiffer than the second material wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the lower teeth wherein the top side of the base does not contact the top teeth of the user when the base is worn in the mouth of the user.

Adell merely teaches a method for making a dental appliance made of an elasticized acrylic containing embedded nylon fibers including the steps of heating the thermoplastic material, forming it onto a dental cast, and cooling it to a rigid state. Further, Adell teaches that the fibers may be arranged in various patterns within the elasticized acrylic to act on the arch through the elasticized acrylic. Moreover, Adell teaches that the appliance may be used as a tooth positioner, a retainer, a splint, or a base plate.

Neither the '535 patent nor Adell, taken singly or in combination, teaches or suggests a generally U-shaped base having an upper occlusal surface and a lower occlusal surface which are



sized to receive the upper teeth or the lower teeth of the user wherein the upper occlusal surface contacts the upper teeth of the user when the base is placed within the mouth wherein the lower occlusal surface contacts the lower teeth of the user when the base is placed within the mouth of the user wherein the base has an interior surface which substantially surrounds a surface of at least one of the upper teeth and at least one of the lower teeth as required by Claim 1.

Additionally, neither the '535 patent nor *Adell*, taken singly or in combination, teaches or suggests a first dental appliance having a generally U-shaped upper base and a second dental appliance having a generally U-shaped lower base wherein a front portion of the upper base and the lower base is adjacent to the second material and further wherein a rear portion of the upper base and the lower base is adjacent to the first material as required by Claim 14. Further, neither the '535 patent nor *Adell*, taken singly or in combination, teaches or suggests Further, a hinge connecting the second material of the upper base to the second material of the lower base wherein the hinge is made from a third material wherein the third material is stiffer than the first material as required by Claim 14.

Still further, neither the '535 patent nor *Adell*, taken singly or in combination, teaches or suggests the upper occlusal surface and the lower occlusal surface are sized to receive the upper teeth

or the lower teeth of the user wherein the front portion of the upper base and the lower base is adjacent to the second material and further wherein the rear portion of the upper base and the lower base is adjacent to the first material as required by independent Claim 27. Moreover, neither the '535 patent nor Adell, taken singly or in combination, teaches or suggests that the hinge and the first material of the upper base and the lower base attach the upper base and the lower base to the mouth of the user as required by independent Claim 27.

Furthermore, neither the '535 patent nor the Adell, taken singly or in combination, teaches or suggests the step of determining an amount of time the user is required to place the dental appliance within the mouth on a periodic basis wherein the dental appliance has a generally U-shaped base wherein the base has an upper occlusal surface and a lower occlusal surface which is located opposite to the upper occlusal surface wherein the upper occlusal surface and the lower occlusal surface have sockets formed within the base sized to receive at least one or more teeth of the user as required by independent Claim 54.

Additionally, neither the '535 patent nor Adell, taken singly or in combination, teaches or suggests a generally U-shaped base wherein the base is made of a first material and a second material wherein the first material is stiffer than the second material wherein at least one of the sockets is preformed and at least one

of the sockets is customized to a shape of one of the upper teeth wherein the bottom side of the base does not contact the bottom teeth of the user when the base is worn in the mouth of the user as required by Claim 71. Further, neither the '535 patent nor *Adell*, taken singly or in combination, teaches or suggests a generally U-shaped base which is made of a first material and a second material wherein the first material is stiffer than the second material wherein at least one of the sockets is preformed and at least one of the sockets is customized to a shape of one of the lower teeth wherein the top side of the base does not contact the top teeth of the user when the base is worn in the mouth of the user as required by Claim 77.

Moreover, a person of ordinary skill in the art would never have been motivated to combine the teachings of the '535 patent with *Adell* in the manner suggested by the Patent Office in formulating the rejection under 35 U.S.C. §103(a). It is submitted that the question under §103 is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in this art. *In re Simon*, 461 F.2d 1387, 174 USPQ 114 (CCPA 1972).

That elements, even distinguishing elements, are disclosed in the art is alone insufficient. It is common to find elements somewhere in the art. Moreover, most if not all elements perform their ordained and expected functions. The test is whether the

invention as a whole, in light of the teachings of the references in their entirety, would have been obvious to one of ordinary skill in the art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

It is insufficient that the art disclosed components of Applicant's invention, either separately or used in other combinations. A teaching, suggestion, or incentive must exist to make the combination made by Applicant. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988).

With the analysis of the deficiencies of the '535 patent and *Adell* in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the '535 patent and *Adell* to produce the claimed invention. Therefore, *prima facie* obviousness has not been established by the Patent Office as required under 35 U.S.C. §103.

Even assuming that one having ordinary skill in the art could somehow have combined the references applied by the Patent Office, the references still lack the novel features and the novel steps positively recited in independent Claims 1, 14, 27, 54, 71 and 77. Accordingly, Applicant asserts that the rejection of Claims 1, 3-10, 12-15, 18-23, 27-29, 31-37, 39, 48, 49, 51, 53, 54, 56, 62, 63,

70, 71 and 73-82 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 11, 26 and 38 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of Adell and further in view of the '199 patent, Applicant respectfully submits that the rejection has been overcome by the amendment to independent Claims 1, 14 and 27, respectively, and for the reasons that follow.

In the Office Action, the Patent Office alleges:

*Bergersen* '199 discloses providing an orthodontic appliance with lingual tabs 46 in order to assist in keeping the mandible advancing maximally at all times and moving forward (see col. 6, lines 37-46). It would have been obvious to one of ordinary skill in the art to form the appliance of *Bergersen* '535 as modified by Adell with lingual tabs in view of *Bergersen* '199 in order to assist in keeping the mandible advancing maximally at all times and moving forward.

Claim 11 requires lingual tabs adjacent to the occlusal surface wherein the lingual tabs extend rearward into the mouth when the base is placed within the mouth. Claim 26 requires lingual tabs formed within the second dental appliance wherein the lingual tabs extend rearward into the mouth when the second dental appliance is placed within the mouth. Claim 38 requires lingual tabs integrally formed with the lower base wherein the lingual tabs extend rearward into the mouth when the lower base is placed within the mouth.

On the contrary, the '199 patent fails to teach or to suggest the elements of the present invention which are not taught by the '535 patent or Adell, taken singly or in combination, as required by amended independent Claims 1, 14, and 27 from which Claims 11, 26 and 38, respectively, depend. Accordingly, the rejection of Claims 11, 26 and 38 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 24, 55 and 72 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of Adell and further in view of the '851 patent, Applicant respectfully submits that the rejection has been overcome by the amendment to independent Claims 14, 54 and 71, respectively, and for the reasons that follow.

In the Office Action, the Patent Office alleges:

*Bergersen* '851 discloses that it is known in the art to provide a u-shaped orthodontic appliance with a substance lining the tooth cavities, to firmly engage the tooth to hold it in a specific position (see col. 4, lines 11-37). It would have been obvious to one skilled in the art to provide the appliance of *Bergersen* '535 as modified by Adell with a substance as taught by *Bergersen* '851 in order to firmly engage the tooth and adhere the device thereto.

Claim 24 requires a substance located between one tooth of the user and the concave portion wherein the substance enables the concave portion to adhere to one tooth of the user. Claim 55 requires adhering the dental appliance to at least one of the teeth of the user to prevent the dental appliance from slipping within

the mouth when the dental appliance is placed within the mouth. Claim 72 requires a substance on the base wherein the substance prevents the base from slipping within the mouth of the user.

On the contrary, the '851 patent fails to teach or to suggest the elements of the present invention which are not taught by the '535 patent or *Adell*, taken singly or in combination, as required by amended independent Claims 14, 54 and 71 from which Claims 24, 55 and 72, respectively, depend. Accordingly, the rejection of Claims 24, 55 and 72 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claim 41 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '851 patent, Applicant respectfully submits that the rejection has been overcome by the amendment to independent Claim 40, respectively, and for the reasons that follow.

In the Office Action, the Patent Office alleges:

It would have been obvious to one skilled in the art to provide the appliance of Bergersen '535 with a substance as taught by Bergersen '851 in order to firmly engage the tooth and adhere the device thereto.

Claim 41 requires a substance surrounding the upper occlusal surface and the lower occlusal surface. On the contrary, the '851 patent fails to teach or to suggest the elements of the present invention which are not taught by the '535 patent, taken singly or in combination, as required by amended independent Claim 40 from which Claim 41 depends. Accordingly, the rejection of Claim 41

under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claim 60 under 35 U.S.C. §103(a) as being unpatentable over the '535 patent in view of the '199 patent, Applicant respectfully submits that the rejection has been overcome by the amendment to independent Claim 57, respectively, and for the reasons that follow.

In the Office Action, the Patent Office alleges:

It would have been obvious to one of ordinary skill in the art to form the appliance of *Bergersen* '535 with lingual tabs in view of *Bergersen* '199 in order to assist in keeping the mandible advancing maximally at all times and moving forward.

Claim 60 requires lingual tabs formed within the lower base wherein the lingual tabs extend rearward into the mouth when the lower base is placed within the mouth. On the contrary, the '119 patent fails to teach or to suggest the elements of the present invention which are not taught by the '535 patent, taken singly or in combination, as required by amended independent Claim 57 from which Claim 60 depends. Accordingly, the rejection of Claim 460 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

In view of the foregoing remarks and amendments, Applicant respectfully submits that all of the claims in the application are in allowable form and that the application is now in condition for allowance. Further, Applicant submits that neither further search



nor consideration would be necessitated by entry of this Amendment; therefore, entry of this Amendment is proper and should be effected.

If any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

Respectfully submitted,

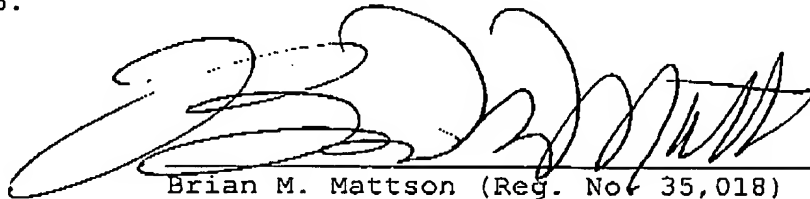


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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this **Amendment After Final and Transmittal Letter** are being transmitted via telefax (571)273-8300 on May 15, 2006.



Brian M. Mattson (Reg. No. 35,018)

FIG. 8

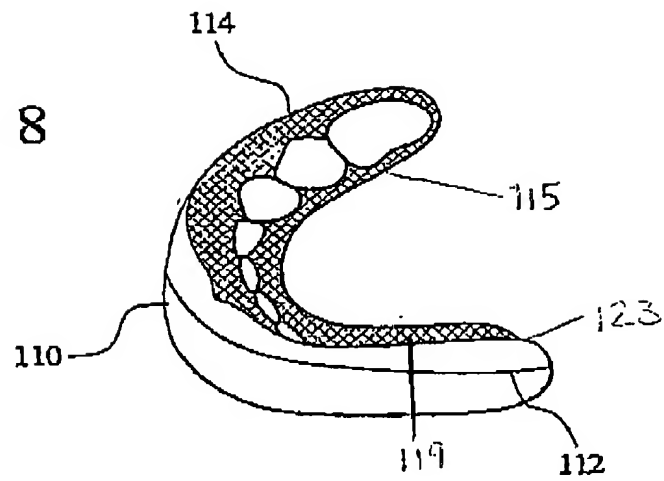


FIG. 9

